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TITLE 22 CALIFORNIA CODE OF REGULATIONS
CHAPTER 4. WATER TREATMENT DEVICES
ARTICLE 1. DEFINITIONS

Section 60400. Certification

"Certification" means that a water treatment device or a treatment component used in water treatment devices has met the testing requirements specified in Section 60435 or the testing requirements accepted by the Department pursuant to Section 4057.1(c) of the Health and Safety Code as defined in Section 60440.

Section 60401. Health or Safety Claim

(a) "Health or Safety Claim" means one or more of the following:

(1) Any claim that the water treatment device or treatment component will remove or reduce a contaminant for which a primary drinking water standard as defined in Health and Safety Code Section 4010.1 or a treatment requirement as authorized in Sections 4023.1(c) and 4023.3(d) of the Health and Safety Code has been established.

(2) Any claim that the water treatment device or treatment component will remove or reduce a contaminant for which a national primary drinking water standard or treatment requirement has been established under the U. S. Safe Drinking Water Act (PL 93-523 and as amended under PL 99-339) (42 U.S.C. Section 300 g-1).

(3) Any claim that the water treatment device or treatment component will remove or reduce a contaminant which has been determined to present a health risk by the United States Environmental Protection Agency pursuant to Sections 1445(a)(2) and 1445(a)(3) of the U.S. Safe Drinking Water Act (PL 93-523 and as amended under PL 99-339) (42 U.S.C. Section 300 j-4(a)(2) and (a)(3)).

Section 60402. Independent Laboratory

"Independent Laboratory" means a laboratory that is neither owned or operated by the manufacturer or an entity which is a parent or subsidiary company to the manufacturer of a water treatment device or treatment component nor is in a partnership with the manufacturer or an entity which is a parent or subsidiary company to the manufacturer.

Section 60403. Manufacturer

(a) "Manufacturer" means any person, as defined by Section 4057(c) of the California Health and Safety Code, that makes, converts, constructs, or produces water treatment devices or treatment components for the purpose of sale, lease or rent to individuals, corporations, associations, or other entities. Manufacturer also includes:

(1) Persons that assemble water treatment devices or treatment components from components manufactured by another entity.

(2) Persons who add their own product name or product identification to water treatment devices or treatment components which have been manufactured or assembled by another entity.

Section 60404. Recognized Testing Organization

"Recognized Testing Organization" means an independent laboratory which has been accredited by the Department pursuant to Health and Safety Code, Division 1, Part 2, Chapter 7.5, Section 1010 et seq.

Section 60405. Testing Requirements

"Testing Requirements" means the contaminant reduction and general performance requirements pursuant to Section 60435.

Section 60406. Modification

"Modification" means any change made to a certified water treatment device or certified treatment component which may affect its performance in meeting the testing requirements or any change in the health or safety claims made with respect to the certified water treatment device or certified treatment component.

ARTICLE 2. CERTIFICATION REQUIREMENTS

Section 60407. Certification Period

The certification shall be valid for one year and shall be renewable for a period not to exceed five years .

ARTICLE 3. APPLICATION REQUIREMENTS

Section 60410. Certification Application

(a) Application for certification shall be submitted by the manufacturer for each water treatment device or treatment component.

(b) A completed application shall include the following:

- (1) Applicant business name, address, and phone number.
- (2) A contact person, address, and phone number.
- (3) The identification of each and every specific contaminant for each and every health or safety claim which is made for the water treatment device or treatment component.
- (4) Product design specifications and engineering information, including blueprints or similar drawing which will provide detailed information about the construction of the water treatment device and treatment components.
- (5) Parts list for the water treatment device or treatment component.
- (6) Test data and verification as prescribed by Sections 60435, 60445, 60450 or 60455.
- (7) A list of all names, model numbers, or other product identifications which are used by the manufacturer to describe the water treatment device or treatment component.

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(8) A statement containing the following declaration by the manufacturer: "This water treatment device or treatment component, which is identified as (insert name, model number, or other product identification) has been toxicologically reviewed and tested to verify that no substances are contributed by the unit to the treated water at levels that would adversely affect the health of the users. The toxicological review and testing was conducted pursuant to the requirements of the material review and qualifications procedures contained in the appropriate test standard referenced in Table I of Section 60435 or Table II of Section 60450".

(9) The application shall be signed by a person in a principal management position.

Section 60415. Certification Renewal

(a) A completed application for renewal of a certification shall be submitted by the manufacturer. A completed application shall include the following:

(1) Applicant business name, address, and phone number.

(2) A contact person, address, and phone number.

(3) A written statement that identifies any change to the information provided as prescribed in Section 60410(b)(7) and (8) or changes to Section 60410(b)(4) and (5) which do not constitute modifications.

(4) The application shall be signed by a person in a principal management position.

(b) The manufacturer shall be responsible for making application for renewal of a certification at least 30 days prior to the expiration date. If the application is submitted after that date, a late application penalty must be paid.

(c) In the event that the application for renewal of the certification is denied by the department, the manufacturer will be notified by registered mail of the denial and the reasons for the denial. The manufacturer may appeal the denial in accordance with Government Code, Title 2, Division 3, Chapter 5, Section 11500 et seq. The registered letter providing notice of the denial will be considered the accusation within the appeal process.

Section 60425. Modification of a Certification

(a) Any modification made to a certified water treatment device or certified treatment component without the written approval of the Department shall void the certification.

(b) Application to modify an existing certification shall be submitted by the manufacturer. A completed application for the modification of a certified water treatment device or certified treatment component shall include the following:

(1) Applicant business name, address, and telephone number.

(2) Name of a contact person, address, and telephone number.

(3) A statement of the reasons for the modification(s).

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- (4) A description of the modification(s) to the certified water treatment device or certified treatment component such as changes in the health or safety claims; changes in treatment components; changes in parts which are in direct contact with the influent or product water; or changes to parts which affect the treatment process or product safety.
- (5) Test data and verification in accordance with the testing requirements in Section 60435, Section 60455 or the manufacturer's testing protocol accepted by the Department pursuant to Section 4057.1(c) of the Health and Safety Code, as defined in Section 60440, for new health and safety claims or test data and verification which substantiates the effect of the modification(s) on the performance of the water treatment device or treatment component in meeting the testing requirements.
- (6) Changes to the parts list provided pursuant to Section 60410(b)(5).
- (7) Changes to the product design, specifications and engineering information including blueprints or similar drawings provided pursuant to Section 60410(b)(4).
- (8) Changes to the list of names, model numbers, or other product identifications provided pursuant to Section 60410(b)(7).
- (9) A statement containing the following declaration by the manufacturer: "This water treatment device or treatment component, which is identified as (insert name, model number, or other product identification) has been toxicologically reviewed and tested to verify that no substances are contributed by the unit to the treated water at levels that would adversely affect the health of the users. The toxicological review and testing was conducted pursuant to the requirements of the material review and qualifications procedures contained in the appropriate testing standard referenced in Table I of Section 60435 or Table II of Section 60450".
- (10) The application shall be signed by a person in a principal management position.

Section 60430. Processing Time

- (a) Within 45 calendar days of receipt of an application for certification, or modification of a certified water treatment device or certified treatment component, the Department shall inform the applicant in writing that the application is complete and accepted for filing, or that it is incomplete and what specific information is needed.
- (b) Within 90 calendar days from the date of filing a completed application for certification or modification of a certified water treatment device or certified treatment component, the Department shall inform the applicant in writing of its decision.
- (c) Within 30 calendar days of receipt of an application for renewal of certification, the Department shall inform the applicant in writing that the application is complete and accepted for filing, or that it is incomplete and what specific information is needed.
- (d) Within 30 calendar days of receipt of a completed application for the renewal of certification, the Department shall inform the applicant in writing that certification has or has not been extended.

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ARTICLE 4. TESTING AND TESTING PROTOCOLS

Section 60435. Testing and Testing Protocols

(a) To be considered for certification, a water treatment device or treatment component shall be tested and found to meet the requirements set forth in Table I.

(b) The testing shall be conducted:

(1) By a recognized testing organization; or

(2) By a manufacturer pursuant to Section 60445.

(c) All contaminant reduction and general performance testing shall be conducted by a laboratory which has been accredited by the Department pursuant to Health and Safety Code, Division 1, Part 2, Chapter 7.5, Section 1010 et seq. Test data submitted pursuant to Section 60450 are exempt from this provision.

Table I
Testing Requirements
TESTING PROTOCOLS

Treatment Process	Reference Standard	Contaminant Reduction Requirements (Sections)	General Performance Requirements (Sections)
Mechanical Filtration	NSF Standard 53 (1)	5.2, 5.2.1, 5.3, 5.3.1, 5.3.2	4.2, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.4
Activated Carbon		5.3.3	5.5
Reverse Osmosis	NSF Standard 58 (2)	5.3, 5.4, 5.4.1, 5.4.2, 5.4.3	4.1, 4.7.2, 4.7.3
Cation Exchange	NSF Standard 44 (3)	5.2, 5.2.1	4.3
Distillation	NSF Standard 62 (4)	5.1, 5.2, 5.3	4.21, 4.5, 4.5.1, 4.5.2, 4.5.2.1, 5.4

Footnotes:

(1) National Sanitation Foundation Standard 53, Drinking Water Treatment Units Health Effects, June 1988.

(2) National Sanitation Foundation Standard 58, Reverse Osmosis Drinking Water Treatment Systems, November 1986.

(3) National Sanitation Foundation Standard 44, Cation Exchange Water Softeners, December 1987.

(4) National Sanitation Foundation Standard 62, Drinking Water Distillation Systems, May 1989.

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Section 60440. Manufacturer's Testing Protocols

- (a) Whenever the testing requirements in Table I of Section 60435 are not applicable for the treatment process or the specific contaminant for which certification is requested, the applicant shall submit proposed testing protocols to the Department for approval prior to the testing of the water treatment device or treatment component.
- (b) The proposed testing protocols shall include the following:
- (1) Testing shall be conducted in duplicate.
 - (2) Testing shall be conducted under pressure and flow conditions typical of the end use of the water treatment device or treatment component.
 - (3) Testing shall provide an equivalent level of assurance that the performance of a water treatment device or treatment component is consistent with the performance of those water treatment devices or treatment components which are tested against the testing requirements prescribed in Table I of Section 60435.

Section 60445. Manufacturer's Test Data

- (a) Test data developed by a manufacturer and submitted to the Department pursuant to the provisions of Section 60435(b)(2) shall meet all of the following requirements:
- (1) The data was obtained using the testing requirements prescribed in Section 60435 or the testing requirements accepted by the Department pursuant to Section 4057.1(c) of the Health and Safety Code as defined in Section 60440.
 - (2) The data was produced by a laboratory which is wholly owned by the manufacturer of the water treatment device or treatment component.
 - (3) The manufacturer has complied with the Department's request for information regarding the qualifications of the laboratory staff, laboratory equipment used for testing and analysis, and records related to the testing under review.
 - (4) The manufacturer's laboratory has been inspected by the Department's staff under a cost reimbursement agreement to recover the cost incurred to make the inspection(s).
 - (5) The manufacturer has performed replicate testing, as specified by the Department, during the on-site inspection. Such replicate testing shall be required when test data submitted pursuant to this section is incomplete or there is reasonable doubt regarding the ability of the treatment process to remove or reduce one or more of the specific contaminants tested.

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Section 60450. Prior Test Data

When a manufacturer submits prior test data to satisfy the requirements of Section 60410(b)(6), the manufacturer shall demonstrate that any test data developed before September 1, 1990 was developed by an independent laboratory or by a manufacturer's laboratory; and that the test data was developed using a testing protocol that was consistent with the applicable testing requirements set forth in Table II. All test data considered by the Department pursuant to this paragraph shall have been produced from testing that was conducted after January 1, 1983.

Table II
Testing Requirements for Prior Data
TESTING PROTOCOLS

Treatment Process	Reference Standard	Contaminant Reduction Requirements (Sections)	General Performance Requirements (Sections)
Mechanical Filtration	NSF Standard 53(1)	5.2, 5.2.1, 5.3, 5.3.1, 5.3.2	4.2, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.4
Activated Carbon		5.3.3	5.5
Reverse Osmosis	NSF Standard 58(2)	5.3, 5.4, 5.4.1, 5.4.2, 5.4.3	4.1, 4.7.2, 4.7.3
Cation Exchange	NSF Standard 44(3)	5.2, 5.2.1	4.3
Distillation	NSF Standard 62(4)	5.1, 5.2, 5.3	4.21, 4.5, 4.5.1, 4.5.2, 4.5.2.1, 5.4

Footnotes:

(1) National Sanitation Foundation Standard 53, Drinking Water Treatment Units Health Effects, June 1988.

(2) National Sanitation Foundation Standard 58, Reverse Osmosis Drinking Water Treatment Systems, November 1986.

(3) National Sanitation Foundation Standard 44, Cation Exchange Water Softeners, December 1987.

(4) National Sanitation Foundation Standard 62, Drinking Water Distillation Systems, May 1989.

Section 60455. Extrapolation of Data

(a) Where a manufacturer has several water treatment devices or treatment components each using the same treatment technology and they are of similar construction, the manufacturer may submit test data developed pursuant to Section 60435 or the manufacturer's testing protocol accepted by the Department pursuant to Section 4057.1(c) of the Health and Safety Code, as defined in Section 60440, on one water treatment device or treatment component as representative of the others under the following conditions:

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- (1) The manufacturer submits evidence that extrapolation will provide test data that is reasonably consistent with empirical data that would be obtained from the actual testing of the water treatment device or treatment component.
- (2) Extrapolation is limited to the scaling up or down in size as measured by the volume of product water produced or volume of water to be treated.
- (3) Scaling up shall be limited to three times greater than the size of the representative water treatment device or treatment component.
- (4) Scaling down shall be limited to one third the size of the representative water treatment device or treatment component.

Section 60460. Retesting

(a) The manufacturer shall retest each certified water treatment device or certified treatment component every five years from the date of certification to insure continued compliance with this chapter and shall submit the results to the Department along with the application for recertification.

(b) The manufacturer shall retest a certified water treatment device or certified treatment component for the reduction of a contaminant or for a general performance requirement when the Department determines through testing pursuant to Section 60435 or the manufacturer's testing protocol accepted by the Department pursuant to Section 4057.1 of the Health and Safety Code, as defined in Section 60440, that the water treatment device or treatment component is not meeting a requirement when the water treatment device or treatment component is used according to the manufacturer's instructions. The manufacturer shall comply with the following requirements when retesting pursuant to this paragraph:

(1) Retesting pursuant to subsection (b) shall be conducted by a recognized testing organization in accordance with Section 60435 or the manufacturer's testing protocol and shall be initiated within three months of notification by registered mail of the Department's determination.

(2) The results of retesting shall be submitted to the Department within 60 days of initiating the testing.

(3) The results of retesting shall be in conformance with Section 60435 or the manufacturer's testing protocol. Manufacturers of certified water treatment devices or certified treatment components determined to be out of compliance with Section 60435 or the manufacturer's testing protocol will be notified by registered mail of the decertification and reason for decertification. The manufacturer may appeal the decertification in accordance with Government Code, Title 2, Division 3, Chapter 5, Section 11500 et seq. The registered letter providing notice of the decertification will be considered the accusation within the appeal process.

(c) Retesting pursuant to subdivision (a) shall not be required for a certified water treatment device or certified treatment component if the water treatment device or treatment component is listed under a product listing program operated by a nonprofit third party testing organization and subject to the following provisions:

- (1) The listing program is operated by a recognized testing organization.

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- (2) The listing program includes retesting of the water treatment device or its treatment components at least every five years.
- (3) The listing program requires that the manufacturer maintain a quality assurance and quality control program for the manufacturing of the water treatment device or treatment component.
- (4) The listing program includes visits at least every two years to the manufacturing plants to inspect the manufacturing of the water treatment device or treatment component and the quality control records maintained by the manufacturer.

ARTICLE 5. PRODUCT LABELING AND DATA SHEET REQUIREMENTS

Section 60465. Product Labeling

(a) A permanent, clear, and legible plate or label containing the following information shall be securely affixed to each certified water treatment device or certified treatment component so that such plate or label can only be removed with a purposeful effort and the plate or label shall be affixed in a readily accessible location:

- (1) Equipment name.
- (2) Model designation.
- (3) Name of manufacturer.
- (4) The statement "For conditions of use, health claims certified by the California Department of Health Services, and replacement parts, see product data sheet."
- (5) The statement "California Department of Health Services Certification Number: XX-XXXX."

Section 60470. Product Data Sheet

(a) Each certified water treatment device shall be accompanied by a Product Data Sheet which includes the following information:

- (1) A copy of the certificate by which the Department has granted certification of the water treatment device. The copy may be incorporated in the product data sheet or attached to the sheet.
- (2) Service flow rate in gallons per minute or gallons per day (liters/day) or the production rate in gallons per day (liters/day).
- (3) Rated service life of the water treatment device (where applicable).
- (4) General use conditions and needs, such as maximum turbidity and bacteriological quality of source water.
- (5) Model or part number and estimated cost of components that must be periodically or routinely replaced to maintain the effectiveness of the certified water treatment device.

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- (6) Maximum and minimum operating temperature in degrees Fahrenheit and degrees Centigrade.
- (7) Maximum and minimum operating pressure in pounds per square inch and kilograms per square centimeter.
- (8) A reference to the owner's manual for general operation and maintenance requirements, and the manufacturer's warranty.

ARTICLE 6. FEES

Section 60475. Fees

(a) The fees specified shall be paid pursuant to the requirements of this chapter. The fees paid are non-refundable:

- (1) Certification or Recertification \$1,400
- (2) Annual Renewal \$400
- (3) Late Renewal Penalty \$200
- (4) Modification of a Certification \$300

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